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Good Laboratory Practices and Safety Assessments: Another View

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In a letter responding to an article by Myers et al. (2009), Becker et al. (2009) claimed that industry's Good Laboratory Practices (GLP)-compliant studies are superior to traditional academic peer-review in predicting the risk of toxic agents. I have read almost 30,000 experimental, etiologic, and epidemiologic papers (most in part), and it is evident that industry GLP studies do not report the same risks of a chemical when published in peer-reviewed studies from academia. This may be explained by biases in industry experiments and epidemiology, especially in design, due to the financial interests of industry sponsors—some receiving billions of dollars in revenue per chemical each year. For pharmaceuticals, dozens of published reviews show a strong correlation between industry sponsorship and findings of safety; I know of four such strong correlations in studies of industrial chemical risks (Bekelman et al. 2003; Fagin and Lavelle1999; Swaen and Meijers1988; vom Saal and Hughes 2005).

Becker et al. (2009) relied on a commentary by a former editor at the *Nature* research journals (Jennings 2006) to claim that peer-review gives inferior data compared with GLP studies. Actually, Jennings (2006) wrote about improving, not abandoning, peer review. He presented data showing that the long-term value of scientific papers in neuroscience (judged by experts) correlates with the quality of the journals in which they were published (based on impact factor). That is a cardinal finding because industry supports various journals and their scientific associations, but their GLP studies are rarely published in high-quality journals (again, based on my readings). Evidently, industry's GLP data are not reliable enough to publish, while financial independence of authors and editors, as well as peer review, are markers of good quality data.

Since the widespread experimental testing frauds at Industrial Bio-Test Laboratories (Schneider 1983) and Craven Laboratories (U.S. Environmental Protection Agency 1994), which generated the GLP reforms, industry has issued oceans of GLP-compliant studies for submission to regulatory agencies. Few are submitted for publication, but almost all (in my experience) are submitted to journals that publish many industry-sponsored studies.

Critically, industry and their regulatory agencies took the opportunity proferred by the requirement to comply with GLP to exclude almost all academic high-quality, non-GLP studies from risk assessments of existing chemicals (and the toxicity of new agents are primarily evaluated by the parties who want to sell it). For existing chemicals, I have always found that the effective toxicity doses in regulatory (GLP) studies are higher than those in the peer-reviewed literature, for several end points.

It is important for individuals who value the contributions that science makes to society (reliable data)—or those who are cautious about toxicity of low-dose and cocktail agents that may affect biochemical signals, especially during development—to continue lobbying public agencies to incorporate academia's peer-reviewed studies and to use disclosure of financial interests to give appropriate credence to industry's data in chemical risk assessments. I also call on independent academics to be less competitive and make their methods and data more freely available.

The author works for scientists and nongovernmental organizations, all of which have financial interests that align with public health.

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Good Laboratory Practices: Becker et al. Respond

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We appreciate the dialogue stimulated by our letter to the editor (Becker et al. 2009). Our intent was to respond only to Myers et al. (2009) regarding the purpose and function of Good Laboratory Practices (GLP) for weighting reliability of studies. Tyl (2009), in response to Myers et al. (2009), provided extensive point-by-point discussion of the specific studies.

In his letter, Tweedale implies that we argued to *a priori* exclude academic, non-GLP studies from risk assessments. To the contrary, we clearly stated that "[e]ach study, GLP and non-GLP, should be evaluated and weighed in accordance with fundamental scientific principles" (Becker et al. 2009). We fully agree with Tweedale that sources of funding should be disclosed, that researchers should "make their methods and data more freely available," and more industry-supported studies should be published in scientific journals. With respect to bias, Maurissen et al. (2005) and Barrow and Conrad (2006) discussed the spectrum of mechanisms in place to ensure the integrity of industry-sponsored research. Ultimately, all scientific research must stand on its merits. However, it is unscientific to eliminate or devalue any study based solely on the organization that conducted the study, the affiliation of an investigator, or the source of funding. The Society of Toxicology (2008) has stated this principle quite clearly: "[r]esearch should be judged on the basis of scientific merit, without regard for the funding source or where the studies are conducted (e.g., academia, government, or industry)."

Moreover, we did not seek to call into question scientific journal peer review per se, but instead to point out that whereas all study records and data from GLP investigations are available to regulatory agencies, rarely are such details made available as part of a peer-reviewed article published in a scientific journal. The point we wish to emphasize is that typical regulatory safety assessment studies conducted in accordance with GLP *a*) must follow agency test guidelines to assure use of relevant test systems, sufficient and applicable dosing protocols, and adequate dose groups and sizes, and *b*) must evaluate specific end points that regulatory organizations consider validated. Further, such GLP studies submitted to regulatory agencies generally include both a full study report and all raw data. This level of scientific rigor and the extensive data of a GLP study allow a regulatory agency to conduct a comprehensive review and to reach a fully independent conclusion. For these reasons, greater weight and confidence are generally afforded to GLP studies. Now, with the increasingly common practice of journals providing access to

supplemental data, there are expanded opportunities for researchers to disseminate actual study data; this should facilitate independent evaluation by regulatory agencies.

As scientists specializing in regulatory safety evaluations, we have extensive experience in interpreting chemical toxicity studies from government, academia, and private-sector laboratories. In conducting chemical risk assessments, we believe that scientists from all sectors should support the use of objective criteria for determining data quality and study reliability (Schneider et al. 2009) coupled with a structured evaluative framework, such as that of the World Health Organization International Programme on Chemical Safety (Boobis et al. 2006, 2008), to provide a systematic approach for assessing the overall weight of the evidence for observed effects and the postulated mode of action. In this manner, data from laboratory experiments, epidemiological investigations, and cutting-edge mechanistic research from all relevant studies—GLP and non-GLP—and from all investigators, regardless of affiliation or funding source, can be comprehensively reviewed, given appropriate weight, and integrated in a manner that provides a robust, biologically plausible understanding of the potential hazards and risks that exposures to a substance could pose.

This letter has been reviewed in accordance with the peer- and administrative-review policies of the authors' organizations. The views expressed here are those of the authors and do not necessarily reflect the opinions and/or policies of their employers.

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ICCVAM: Not Doing Enough

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Anyone interested in the facts about the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and its ineffectiveness, rather than just another ICCVAM/National Toxicology Program (NTP) fluff piece (Birnbaum and Stokes 2010), should read the 2008 front page *Washington Post* exposé of ICCVAM (Gaul 2008) and the PETA report on which the *Post* investigation was based (PETA 2008).

Birnbaum and Stokes' "PR piece" notwithstanding, ICCVAM should be held responsible for failing to abide by its Congressional mandate to support the development and implementation of non-animal testing methods.

Sadly, it appears that the new leadership of the National Institute of Environmental Health Sciences is no more inclined to improve the quality of the science supporting regulatory decision-making than the previous one.

The author is employed by People for the Ethical Treatment of Animals, the largest animal rights organization in the world.

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ICCVAM: Birnbaum and Stokes Respond

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Sandler's comments about our editorial concerning the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (Birnbaum and Stokes 2010) suggest a lack of awareness of the role and significance of the contributions of ICCVAM. The 2008 *Washington Post* article she cites (Gaul 2008) contained many inaccurate statements (a letter correcting the errors was submitted to the *Washington Post,* but it was not published). We appreciate this opportunity to provide accurate factual information about ICCVAM.

ICCVAM is a congressionally mandated committee that does not have laboratories and does not develop test methods or conduct validation studies. Rather, ICCVAM depends on other organizations, including its 15 member agencies, to carry out such activities. The director of the National Institute of Environmental Health Sciences (NIEHS) established ICCVAM in 1997, with the cooperation of 14 other agencies, in order to provide a coordinated interagency process to facilitate the regulatory acceptance of scientifically valid alternative methods. As an interagency forum, ICCVAM also coordinates and promotes related issues, including national and international harmonization, guidance on validation studies, and awareness of accepted alternative methods.

ICCVAM was formally established by legislation in 2000 with signing of the ICCVAM Authorization Act of 2000. This law charges ICCVAM to "review and evaluate new or revised or alternative test methods, … including the coordination of technical reviews of proposed new or revised or alternative test methods …." ICCVAM develops and submits recommendations based on its reviews to the Secretary of Health and Human Services for transmittal to federal agencies. Agencies must review the recommendations and respond to ICCVAM within 180 days. ICCVAM has implemented a transparent and scientifically rigorous evaluation process for test methods that has resulted in national and international regulatory acceptance of all recommended test methods. ICCVAM has contributed to the acceptance of 33 alternative test methods, including 17 based on formal comprehensive evaluations (ICCVAM 2010). Recommendations on an additional 4 methods are pending.

The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) administers ICCVAM and provides scientific and operational support for ICCVAM activities. Consistent with the NTP

mission, NICEATM also conducts independent validation studies on new, revised, and alternative test methods, and coordinates international validation studies with its counterparts in Japan, Europe, and Canada (NIEHS 2009).

In 2008, NICEATM and ICCVAM launched a 5-year plan to further reduce, refine, and replace the use of animals in regulatory testing in conjunction with federal agencies and other stakeholders (ICCVAM 2008). The plan seeks to advance alternative test methods of high scientific quality that will continue to protect and advance the health of people, animals, and the environment. The plan emphasizes using new technology to develop predictive systems that will lessen or avoid the need for animals where scientifically feasible.

The NIEHS and NTP support research that may lead to the development of new test methods relevant to regulatory testing. These include the Tox21 collaboration between the NTP, the National Institutes of Health Chemical Genomics Center, and the U.S. Environmental Protection Agency (Schmidt 2009). The Tox21 initiative is the largest *in vitro* toxicology research program ever conducted worldwide and is expected to yield candidate methods and approaches with potential applicability to regulatory testing. Following standardization and validation in consultation with ICCVAM, methods with regulatory applicability will be reviewed by ICCVAM and recommendations forwarded to appropriate agencies.

ICCVAM has been enormously successful in gaining regulatory acceptance of alternative methods (ICCVAM 2010). Gaining regulatory acceptance requires high-quality studies that prove that the alternative test methods will provide the same or better level of protection of workers and consumers as the methods they might replace. The test method must also be shown to be reproducible in different laboratories.

The animal welfare benefits of ICCVAM's work are evidenced by many examples. These include an alternative test for acute oral toxicity that has replaced the LD_{50} test (median lethal dose), which used as many as 200 animals per test, with the Up-and-Down Procedure (UDP), which uses only 7 animals on average per test (NIEHS 2001; Organisation for Economic Co-operation and Development 2008). The UDP and other alternative test methods have profoundly reduced animal use for acute oral toxicity testing, which is conducted to determine the poisoning potential of chemicals and products and is the most commonly conducted safety test worldwide.

Another landmark ICCVAM contribution is the reduction and refinement of animal use for eye-safety testing. ICCVAM evaluated and recommended the first two *in vitro* test methods that can now be used to determine whether substances can cause blindness and other severe eye damage, without the need for live animals (NIEHS 2008). Based on ICCVAM's evaluation, these test methods were adopted as international test guidelines in 2009.

In summary, ICCVAM has demonstrated its effectiveness and value in achieving the regulatory acceptance of test methods that reduce, refine, and replace animal use. Most importantly, by making appropriate science-based decisions, ICCVAM has ensured that such methods will continue to protect the public's health and safety. We expect ICCVAM to serve an increasingly important role in translating research advances into improved test methods that will benefit both people and animals.

The authors declare they have no competing financial interests.

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Polyethylene Terephthalate and Endocrine Disruptors

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In the commentary "Polyethylene Terephthalate May Yield Endocrine Disruptors," Sax (2010) theorized that bottles made of polyethylene terephthalate (PET) might leach phthalate ester plasticizers and/or antimony to produce endocrine-disrupting effects. On behalf of the North American producers of PET resin, I have the following comments and corrections.

Phthalate ester plasticizers are not used to manufacture polyethylene terephthalate and never have been. It is not chemically plausible for PET to produce these phthalate esters.

Sax (2010) did suggest that some reports of phthalate esters in PET bottled water containers may have originated from contamination of the bottled water, or from phthalate ester contamination of recycled PET used in manufacturing water and beverage containers. In addition, non-PET components of bottled water containers (e.g., closures) might be another possible source. Whatever the origin of phthalate esters, which could not be identified in any of the studies cited by Sax, it is clearly unreasonable to ascribe PET as the source.

Regarding antimony, Sax noted that Choe et al. (2003) reported antimony chloride as showing high estrogenicity. However, antimony oxides—not antimony chloride—are used as catalysts in the manufacture of PET. Antimony oxides are chemically and toxicologically distinct from antimony chlorides. No study has reported finding toxic amounts of antimony in PET-bottled water or beverages.

PET bottles and containers meet all applicable U.S. and international safety requirements for food contact, and the inert qualities of PET define its preferred use for many food, beverage, and medical applications. Consumers can feel confident about the safety of PET food and beverage containers.

We welcome dialogue with researchers and regulatory agencies on the chemistry and safety of PET resin.

The author is employed as the Executive Director of the PET Resin Association, the industry association representing North American producers of polyethylene terephthalate.

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Sax L. 2010. Polyethylene terephthalate may yield endocrine disruptors. Environ Health Perspect 118:445–448.

Polyethylene Terephthalate: Sax Responds

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In his letter Vasami reminds readers that phthalates are not used in the manufacture of PET. Indeed, I emphasized precisely this point in my commentary (Sax 2010), for example, when I stated that "phthalates are not used as substrates or precursors in the manufacture of PET." Vasami also asserts that "it is not chemically plausible for PET to produce these phthalate esters"; however, I never suggested that virgin PET gives rise to phthalate esters via degradation of PET itself. I did cite multiple studies in which phthalates were recovered from the contents of PET bottles—as contaminants leaching from the PET bottle wall. How did the phthalates come to be there? As I noted, one possibility is that some of the PET used in manufacturing the bottles may have been recycled PET, and some of this recycled PET might have been contaminated with phthalates. Again, as I noted in my commentary, PET is commonly used for bottling a variety of products (e.g. shampoo) that are known to contain phthalates; these phthalates can then sorb into the PET bottle. Other researchers have previously documented that various organic substances readily migrate into PET (e.g., Komolprasert and Lawson 1997). Indeed, previous investigators have documented the presence of phthalates in PET bottles marketed for consumer use (e.g., Kim et al. 1990); Nerín et al. (2000) reported that the concentration of phthalates was much higher in recycled PET material than in virgin PET.

There are good environmental arguments for recycling plastics rather than disposing of them in landfills. The potential for tension between the desire to recycle plastics, on the one hand, and the desire to protect human health, on the other hand, has long been recognized (e.g., Castle 1994). Reconciling these two objectives requires a better understanding of the origin of endocrine disruptors in PET.

Vasami notes that although Choe et al. (2003) reported antimony chloride as showing high estrogenicity, "antimony oxides—not antimony chloride—are used as catalysts in the manufacture of PET." Although Vasami asserts that antimony oxides "are chemically and toxicologically distinct from antimony chlorides," the toxicological literature does not provide strong support for this assertion. Antimony chloride, when combined with water, readily forms antimony oxide (National Research Council 2000), and both antimony chloride and antimony oxide ionize *in vivo*. Merski et al. (2008) reported that when animals were fed ground PET, antimony was recovered from their urine in a dose-dependent fashion. Toxicologically, what seems to matter is the antimony and its oxidation state [trivalent (III) or pentavalent (V)], not the anion (chloride or oxide). Antimony(III) is the ionization state in the antimony oxide used in the production of PET; the same ionization state (III) is found in antimony chloride. Using X-ray spectrometry, Martin et al. (2010) confirmed that the antimony in PET bottle walls is in fact trivalent antimony. The toxicological literature clearly establishes that trivalent antimony is far more toxic to humans than is pentavalent antimony (e.g., Chulay et al. 1988; De Boeck et al. 2003; Phillips and Stanley 2006). Vasami's implication that antimony(III) oxide, when ingested, might be free of the risks demonstrated for antimony(III) chloride, is without evidentiary basis.

Vasami concludes by reminding readers that PET bottles meet all applicable safety requirements. However, he neglects to note that these safety requirements were developed largely in the 1980s and 1990s, when the chief concern about antimony and other metalloids had to do with carcinogenicity (e.g., De Boeck et al. 2003) and organ toxicity (e.g., Poon et al. 1998). The standards were developed based on doses believed to be carcinogenic and/or directly toxic. The ability of inorganic metalloids such as antimony to act as xenoestrogens has only recently been recognized (Darbre 2006). More research is needed to determine whether the regulatory requirements for antimony in foods and beverages should be adjusted in order to minimize the risk of endocrine-disrupting effects.

Certainly there is a paucity of research on the endocrine-disrupting effects of antimony. But surely the remedy for this deficiency is more research, not a stubborn insistence that what we don't know can't hurt us.

The author declares he has no competing financial interests.

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Erratum

In the article "Using National and Local Extant Data to Characterize Environmental Exposures in the National Children's Study: Queens County, New York" by Lioy et al. [Environ Health Perspect 117:1494–1504 (2009)], Shahnaz Alimokhtari was inadvertently omitted as an author. The corrected author names and affiliations are listed below.

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The authors apologize for the error.